K071183

JUL 20 2007

WaveLight

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

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Summary Preparation Date:	April 17, 2007

2. Names

Device Name:	ALLEGRO Oculyzer
Classification Name:	Ophthalmic Camera Product Code: MXK Panel: Ophthalmology

3. Predicate Devices

The ALLEGRO Oculyzer system is substantially equivalent to the Oculus Pentacam Scheimpflug Camera system (K030719).

4. Device Description

The ALLEGRO Oculyzer Scheimpflug Camera is based on the Scheimpflug principle for slit lamp photography. The system is table mounted and AC powered by an external power supply.
The system contains
(a) measuring devices including:

- illumination unit with LED's, 475nm wavelength UV-free to illuminate the anterior segment of the eye,
- a CCD-Camera unit to take the Scheimpflug Images,

- a CCD-Camera unit in the center for the fixation monitoring and internal correction,
- a optical lens system to project the slit,
- two infrared LED's to illuminate the pupil for fixation monitoring.

(b) electrical devices, including:

- a memory board and a CPU and which stores and analyses the taken images.
- a power supply board which prepares and controls the electrical conditions of the ALLEGRO Oculyzer Scheimpflug system
- an electric motor for rotating
- a communication board for transferring the images to external standard high speed PC's (part of the device)

All the mentioned parts are mounted internal the system and the housing around separates this parts from any external illegal operation.

The measurement can be done in two different ways, depending of what you like to evaluate:

(c) Taking photos from one Camera position:

The Camera takes pictures from one fixed position as it is already well known from the common Scheimpflug Cameras. The intended use is to get information of the condition of the lens.

(d) Taking photos from several positions:

The Camera rotates around the eye and takes up to 50 Scheimpflug Images from several positions. Every single picture has 500 measured true elevation points. So in the summary we get 25.000 measured true elevation points. The Scheimpflug Images taken during the examination are digitalized in the system. All Image Data are transferred to the external PC. When the examination is finished, the PC calculates a three dimensional mathematical model from which all additional information is derived.

The intention is to get information about
- anterior and posterior surface of the cornea,
- thickness of the cornea,
- chamber angle, volume and depth.

Other systems which are already on the market and has an FDA admission like the Orbscan II™ Keratometer, measured at the beginning about 9.000 true elevation points and now about 18.000 measurement points at all. This instrument calculates the pachymetry and the posterior surface using the measured points, too.

There is also a device called Pentacam Scheimpflug Camera. As the WaveLight Device consists of the Measuring device from Oculus the WaveLight device fulfills the same technical specifications. Also the software includes the same basic functions but is customized to the WaveLight Corporate Design.

5. Indications for Use

The ALLEGRO Oculyzer is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye.
To evaluate:
- corneal shape
- analyse conditions of the lens (opaque crystalline lens)
- analyse the anterior chamber angle
- analyse anterior chamber depth
- analyse the volume of the anterior chamber
- analyse anterior and posterior cortical opacity
- analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross lit images with densitometry
- corneal thickness.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

WaveLight AG
c/o Ralph Saettele
Am Wolfsmantel 5
91058 Erlangen
Germany

JUL 20 2007

Re: K071183
Trade/Device Name: ALLEGRO Oculyzer
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: July 09, 2007
Received: July 11, 2007

Dear Mr. Saettele:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071183
Device Name: ALLEGRO Oculyzer

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- Corneal shape
- Analyze condition of the lens (opaque crystalline lens)
- Analyze the anterior chamber angle
- Analyze the anterior chamber depth
- Analyze he volume of the anterior chamber
- Analyze the anterior and posterior cortical opacity
- Analyze the location of the cataracts (nuclear, subcapsular and or cortical), using cross-lit images with densitometry
- Corneal thickness

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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